

REMARKS/ARGUMENTS

Claims 18-30 are currently pending in the above-identified application. No claims have been amended in the present response. Applicants respectfully request reconsideration of the pending claims in light of the remarks below.

Rejections Under 35 U.S.C. §102

Claims 18, 19, and 22 remain rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,338,686 (hereinafter Hellerstein). In particular, the Examiner has asserted that Hellerstein teaches a method for determining the rate of degradation of an isotopically labeled biopolymer comprising adding a stable isotope-labeled subunit to a biopolymer pool, collecting first and second samples and measuring the relative abundance of monoisotopic and isotopomeric peaks using mass spectrometry, calculating the difference between the peaks of the first and second samples and determining the rate of polymer degradation. In addition, the Examiner has asserted that Hellerstein teaches the collection of serial time points and the plotting over time of individual mass isotopomers to determine the rate of decay. It is alleged by the Examiner that Hellerstein teaches every element of the claimed invention.

Further, the Examiner asserts that Hellerstein uses mass spectrometry for his calculations which Applicants state, in their specification on page 2, is a problem. It is noted by the Examiner that Applicants use mass spectrometry in their example and that they state on page 13 that mass spectrometry can be used for the calculations. The Examiner believes that as Applicants have used open language in their claims the use of mass spectrometry is not precluded. Finally, the Examiner alleges that Hellerstein teaches that any calculation means which provides relative values for abundance of isotopomers in a sample may be used in describing data.

Applicants must again respectfully disagree with the rejection of the Examiner. In particular, the Examiner asserts that Hellerstein teaches calculation of relative abundance of isotopomers in determining the rate of decay of a biopolymer. This is not the case.

Hellerstein teaches a method where molar excesses are calculated, ratios of the excesses are determined and these values are used to obtain estimates of the proportion of mass isotopomers in the subunit precursor pool and biosynthetic rates and measurements of rates of isotopic decay. (See for example the description of Fig. 1, column 3, lines 23-28 and throughout the specification). The calculation of molar excesses are not the same as the determination of abundance used in the steps of the present invention. In addition, the Examiner has stated that Hellerstein teaches every element of the claimed invention. Further, the Examiner notes that Hellerstein uses mass spectrometry for his calculations and further alleges that Applicants state in their specification that use of mass spectrometry is a problem. These assertions and allegations are incorrect.

Hellerstein does not teach the determination of relative abundance of monoisotopic and isotopomeric peaks in first and second samples. Instead, Hellerstein teaches the calculation of molar excesses of isotopomers. Further, Applicants do not state that use of mass spectrometry is a problem. On the contrary, Applicants teach that the use of stable isotopes for analyzing the incorporation of a probe into biopolymers during in vivo metabolic studies has several problems including 1) the need to breakdown the biopolymer of interest into smaller components (often amino acids), 2) the need to chemically derivatize the components followed by separating the components within their classes (often by gas-chromatography); and 3) analyzing the mass of each component using a mass spectrometer. It is the combination of factors that contribute to the difficulties, not the use of mass spectrometry in isolation.

The Examiner has also noted that in column 7, lines 1-6 that Hellerstein allegedly teaches that any calculation means which provides relative values for abundance of such

isotopomers in a sample may be used in describing data. Applicants believe that this statement has been taken out of context. The statement actually reads:

Measured mass spectral peak heights may be conveniently expressed as ratios toward the parent (zero mass isotope) isotopomer for purposes of determining the relative frequencies of at least two different mass isotopomers of the biopolymer molecule. As will be appreciated from the ensuing discussion, the isotopomers analyzed will contain at least one mass isotopically labeled subunit, and, for purposes of comparison, it is convenient to express the mass spectral peak height as ratios, using the peak height of the zero mass isotope parent compound as denominator, though it is appreciated that any calculation means which provides relative values for the abundances of such isotopomers in a sample may be used in describing such data, for the purposes of the invention.

(Hellerstein column 6, line 60 - column 7, line 6)

As can be seen from the complete quote Hellerstein is not providing any guidance to the skilled artisan that the relative abundance can be used to directly calculate the decay of a biopolymer, but is used merely as a value in the more complex calculation of the relative frequencies of at least two different mass isotopomers of the biopolymer. Reconsideration and withdrawal of the rejection of claims 18, 19 and 22 under 35 U.S.C. § 102(b) as anticipated by Hellerstein is respectfully requested.

B. ROBERT FRANZA JR. *et al.*
Application No. 10/722,161
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1636

PATENT


Applicants note that the Examiner has indicated that claims 20, 21, and 23-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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